Michael J. Williams, Esq.
CELLINO & BARNES
2500 Main Place Tower
350 Main Street
Buffalo NY 14202-3725
Tel: 800.888.8888 Fax: 716.854.6291
E-mail: michael.williams@cellinoandbarnes.com
Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JOAN WARD and ALAN LIEBOWITZ Plaintiffs, v. DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON INTERNATIONAL Defendants	CASE NO: JUDGE: DEPT: CIVIL COMPLAINT FOR DAMAGES

Plaintiffs Joan Ward and Alan Liebowitz, by and through undersigned counsel, sue Defendants DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., and JOHNSON & JOHNSON INTERNATIONAL, and for their Complaint allege, upon information and belief and based on the investigation to date of their counsel, as follows:

NATURE OF THE ACTION

1. Defendants manufactured the Pinnacle Hip Implant Device ("Pinnacle Device") including the Pinnacle Acetabular Cup System beginning in 2001. The Pinnacle Device was designed, developed, marketed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be permanently implanted. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Devices as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you – and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device(s) as superior devices including TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

2. Defendants also advertised and sold Pinnacle Devices as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

3. On information and belief Plaintiffs allege that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of Pinnacle Hip components are still in use today."

4. On information and belief, Plaintiffs allege that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of Pinnacle Devices.

5. Literature relating to Pinnacle hips demonstrates that since at least 2006 DePuy was on notice of design problems showing that the Pinnacle metal-on-metal hip implant, like DePuy's ASR hip, have a propensity to deform which can lead to edge loading and loosening, increased wear and metal ion dispursion.

6. An article published in September, 2006, in the Journal of Arthroplasty reported an exceptionally high rate of acetabular component deformation. This study reported that "90.5% of [Pinnacle] cups showed measurable compression deformity…[which] may result in negative clinical consequences such as equatorial loading with increased wear and potential seizing of components…or locking mechanism damage."

7. An article published in December, 2010 in the Journal of Orthopaedic and Trauma Surgery reported significantly increased serum levels of cobalt and chromium three months post-operatively in patients implanted with metal-on-metal 36-mm Pinnacle femoral head hips.

8. On information and belief, Plaintiffs allege that Defendants are aware that Pinnacle Devices may result in metallosis, biologic toxicity, and high failure rate including pain, disability and lack of function. Plaintiffs further allege that Pinnacle Devices may result in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiffs further allege that Defendants are aware that metal particles from Pinnacle Devices may result in metallosis, tissue death, bone erosion, and development of tumors.

9. On information and belief, Plaintiffs allege that particulate debris from Pinnacle Devices can cause severe inflammation, severe pain, tissue and bone loss, and other related diseases.

10. Plaintiffs further allege that Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because Plaintiffs are citizens of a State which is different from the States where DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON

SERVICES, INC. and JOHNSON & JOHNSON INTERNATIONAL (hereinafter "Defendants") are incorporated and have their principal places of business.

12. The amount in controversy, exclusive of interest and costs, exceeds SEVENTY-FIVE THOUSAND DOLLARS ($75,000.00).

13. Venue is appropriate in this District pursuant to 28 U.S.C. §1391, *et. seq.*, because a substantial part of the events giving rise to this claim occurred in this Judicial District.

14. Defendants were at all times relevant herein doing business in and/or directed activities in California, and specifically in this judicial district.

15. Defendants transacted, solicited and conducted business and derived substantial revenue from such business in the State of California and in this district in particular.

PARTIES

16. Plaintiff, Joan Ward, is a natural person and citizen of the County of Marin, State of California.

17. Plaintiff, Alan Liebowitz, is a natural person and citizen of the County of Marin, State of California.

18. Defendant DEPUY ORTHOPAEDICS, INC. is an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. This defendant is a resident and citizen of Indiana.

19. At all times material hereto, Defendant DEPUY ORTHOPAEDICS, INC. developed, tested, assembled, manufactured, packaged labeled, prepared, distributed, marketed, supplied, and/or sold Pinnacle Devices, either directly or indirectly, to members of the general public throughout the United States.

20. Upon information and belief, at all relevant times, DEPUY ORTHOPAEDICS, INC. was present and doing business in the State of California and in the Northern District of California in particular.

21. At all relevant times, DEPUY ORTHOPAEDICS, INC. transacted, solicited, and conducted business in the State of California and derived substantial revenue from such business.

22. At all relevant times, DEPUY ORTHOPAEDICS, INC. expected or should have expected that its acts would have consequences within the United States and in the Northern District of California in particular.

23. Defendant DEPUY, INC. is an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. DEPUY, INC. is a resident and citizen of Indiana.

24. At all times material hereto, DEPUY, INC. developed, tested, assembled, manufactured, packaged labeled, prepared, distributed, marketed, supplied, and/or sold Pinnacle Devices, either directly or indirectly, to members of the general public throughout the United States.

25. Upon information and belief, at all relevant times, DEPUY, INC. was present and doing business in the State of California and in the Northern District of California in particular.

26. At all relevant times, DEPUY, INC. transacted, solicited, and conducted business in the State of California and derived substantial revenue from such business.

27. At all relevant times, DEPUY, INC. expected or should have expected that its acts would have consequences within the United States and in the Northern District of California in particular.

28. Defendant JOHNSON & JOHNSON is a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. JOHNSON & JOHNSON is a resident and citizen of New Jersey.

29. At all times material hereto, JOHNSON & JOHNSON developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or

sold Pinnacle Devices, either directly or indirectly, to members of the general public throughout the United States.

30. Upon information and belief, at all relevant times, JOHNSON & JOHNSON was present and doing business in the State of California in the Northern District of California in particular.

31. At all relevant times, JOHNSON & JOHNSON, transacted, solicited, and conducted business in the State of California and derived substantial revenue from such business.

32. At all relevant times, JOHNSON & JOHNSON expected or should have expected that its acts would have consequences within the United States and in the Northern District of California in particular.

33. Defendant JOHNSON & JOHNSON SERVICES, INC. is a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. JOHNSON & JOHNSON SERVICES, INC. is a resident and citizen of New Jersey.

34. At all times material hereto, JOHNSON & JOHNSON SERVICES, INC. developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Pinnacle Devices, either directly or indirectly, to members of the general public throughout the United States.

35. Upon information and belief, at all relevant times, JOHNSON & JOHNSON SERVICES, INC., was present and doing business in the State of California in the Northern District of California in particular.

36. At all relevant times, JOHNSON & JOHNSON SERVICES, INC., transacted, solicited, and conducted business in the State of California and derived substantial revenue from such business.

37. At all relevant times, JOHNSON & JOHNSON SERVICES, INC., expected or should have expected that its acts would have consequences within the United States, and in the Northern District of California in particular.

38. Defendant JOHNSON & JOHNSON INTERNATIONAL is a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. JOHNSON & JOHNSON INTERNATIONAL is a resident and citizen of New Jersey.

39. At all times material hereto, Defendant JOHNSON & JOHNSON and/or JOHNSON & JOHNSON SERVICES, INC. and/or JOHNSON & JOHNSON INTERNATIONAL, as the parent company of Defendant DEPUY ORTHOPAEDICS, INC. and/or DEPUY, INC. developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Pinnacle Devices, either directly or indirectly, to members of the general public throughout the United States.

40. Upon information and belief, at all relevant times, Defendants were present and doing business in the State of California in the Northern District of California in particular.

41. At all relevant times, Defendants transacted, solicited, and conducted business in the State of California and derived substantial revenue from such business.

42. At all relevant times, Defendants expected or should have expected that its acts would have consequences within the United States and in the Northern District of California in particular.

FACTUAL ALLEGATIONS

43. Defendants' defective device was placed into the stream of interstate commerce by Defendants and was implanted in Plaintiff on or about October 7, 2011.

44. As a direct and proximate result of Defendants placing the product into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages,

including but not limited to: past, present and future physical and mental pain and suffering and debility; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, lost wages, other related damages, as well as damages for loss of consortium.

45. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in her total hip arthroplasty.

46. Plaintiff was unaware of any causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device, due in part to the failures of Defendants to properly warn him and her physicians about the Pinnacle Device's defective and fault nature. Plaintiff recently became aware of said causal link. Plaintiff was unable to make an earlier discovery of said causal link regardless of any reasonable diligence because of Defendants' failure to properly warn her and her physicians about the Pinnacle Device's defective and faulty nature, their failure to report problems with the device, their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

47. As a direct and proximate result of Defendants placing the product into the stream of commerce, Plaintiff's injuries necessitated a revisionary surgery of the left hip on approximately November 25, 2014, and may be expected to require revisionary surgery in the future.

48. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur)

bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

49. Pinnacle Devices are made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal on its outer shell. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium metal.

50. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

51. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including Pinnacle Devices, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

52. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and

when relevant, packing and installation of such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

53. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probably benefit to health from the use of the device against any probable risk of injury or illness from such use.

54. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

55. Rather than being approved for use by the FDA pursuant to the rigorous premarket process, Pinnacle Devices including metal-on-metal total hip replacement systems were certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

56. As such, under the 510(k) process, Defendants were able to market Pinnacle Devices with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

57. Had Defendants conducted clinical trials of Pinnacle Devices before being released on the market, they would have discovered that Pinnacle Devices result in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate and disability due to the release of metal particles in the patient's surrounding tissue including

when the cobalt-chromium metal formal head rotates within the cobalt-chromium metal acetabular liner.

58. Implantation of Pinnacle Devices can result in the early systemic release of high levels of toxic metal cobalt-chromium ions into the hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the femoral head rotating within the liner. The particles that accumulate in the patient's tissue surrounding the implant giving rise to metallosis, toxicity, pain, disability, failure, pseudotumors, or other conditions.

59. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

60. The problems with Pinnacle Devices are similar to the issues that gave rise to Defendants' recall of the ASR Device. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide.

61. Upon information and belief, Plaintiffs allege that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to Pinnacle Devices.

62. Upon information and belief, Plaintiffs allege that many recipients of Pinnacle Devices are suffering from elevated levels of chromium and cobalt. Plaintiffs further allege on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

63. A number of governmental regulatory agencies have recognized the problems that are caused by implants such as the ASR and Pinnacle Devices. For instance, The

Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

64. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

65. Despite the public knowledge to the contrary, Defendants continue to sell, market and misrepresent Pinnacle Devices as high-quality, safe and effective hip replacement products in their marketing and promotional materials regardless of the fact that Defendants have known for years that Pinnacle Devices can pose a danger to patients that have it implanted.

66. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

FEDERAL REQUIREMENTS

67. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

68. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

69. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. §360(i).

70. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device confirm to current good manufacturing proactive, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. *See* 21. U.S.C. §360j(f).

71. Pursuant FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any

information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 CFR §803.50.

72. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 CFR §803.52.

73. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. *See* 21 CFR §803.53.

74. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with the use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR §806.

75. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure

that devices conform to define user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See* 21 CFR §820.

76. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 *et seq*. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

77. Pursuant to 21 CFR §820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

78. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure, responsibilities, procedures, processes and resources for implementing quality management. *See* 21 CFR §820.3(v).

79. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with

the established quality system requirements and to determine the effectiveness of the quality system.

80. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

81. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

82. Pursuant to 21 CFR §820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

83. Pursuant to 21 XCFR §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

84. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

85. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

86. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

87. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; an d

e. Criteria for workmanship which shall be expressed in documented standards or by other equivalent means.

88. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

89. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

90. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

91. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

92. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

93. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

94. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedure to ensure that equipment is routinely calibrated, inspected, checked and maintained.

95. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 CFR §820.3(z)(1)

96. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

97. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

98. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem;

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

DEFENDANTS' PINNACLE ACETABULAR SYSTEM IS A 510(k) APPROVED MEDICAL DEVICE

99. Defendants submitted a §510(k) premarket notification and obtained marketing approval for Pinnacle Device(s) from the FDA under Section 510(k) of the Act. *See* U.S.C. §360 *et seq.*

100. Under the §510(k) approval process, the FDA determined that Defendants' Pinnacle Devices were "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

101. Upon information and belief, Defendants' Pinnacle Devices are adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

102. Upon information and belief, Defendants' Pinnacle Devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

103. Upon information and belief, Defendants' Pinnacle Devices are adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their Pinnacle Devices in accordance with 21 CFR §820 *et seq.,* as set forth above.

104. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for its Pinnacle Device.

105. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Pinnacle Devices were defective and failed, resulting in injuries to the Plaintiff.

106. If Defendants had complied with federal requirements regarding CGMP, Defendants' Pinnacle Devices would have been manufactured properly such that they would not have resulted in injuries to the Plaintiff.

FIRST CAUSE OF ACTION AS AGAINST DEFENDANTS
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against All Defendants)

107. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

108. Defendants are the manufacturers, designers, marketers, distributors, sellers, and/or suppliers of orthopedic devices including Pinnacle Devices.

109. Pinnacle Devices manufactured, designed, marketed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were defective in their manufacture and construction when it left the hands of Defendants in that they deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

110. As a direct and proximate result of the Plaintiff's use of Defendants' Pinnacle Devices, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

111. Defendants' actions and omission as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

112. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION AS AGAINST DEFENDANTS
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against All Defendants)

113. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

114. Defendants are the manufacturers, designers, marketers, distributors, sellers, and/or suppliers of orthopedic devices including Pinnacle Devices.

115. The Pinnacle Devices manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or they were more dangerous than an ordinary consumer would expect, and/or they failed to comply with federal requirements for these medical devices.

116. The foreseeable risks associated with the design or formulation of Pinnacle Devices include, but are not limited to, the fact that the design or formulation of Pinnacle Devices is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

117. As a direct and proximate result of the Plaintiff's use of the Pinnacle Device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or its failure to comply with federal requirements, Plaintiff suffered serious

physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

118. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

119. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION AS AGAINST DEFENDANTS
STRICT PRODUCTS LIABILITY – DEFECT DUE TO
NONCONFORMANCE WITH REPRESENTATIONS

(Against All Defendants)

120. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

121. Defendants are the manufacturers, designers, marketers, distributors, sellers, and/or suppliers of orthopedic devices including Pinnacle Devices.

122. The Pinnacle Devices manufactured and supplied by Defendants were defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning the product and/or with applicable federal requirements.

123. Defendants made representations to consumers regarding the character or quality of Pinnacle Devices, including but not limited to statements that Pinnacle Devices were safe and effective hip replacement systems. For example, Defendants claimed that these devices were based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles." Defendants also advertised that the device is "[d]esigned for active lifestyles." They further asserted that the "DePuy metal-on-metal (MoM) articulation system is leading the way in advanced technology. Through years of careful engineering,

research and expertise, we've created a total hip replacement solution that offers low wear and high stability." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

124. The Plaintiff and/or her physicians justifiably relied upon Defendants' representations regarding Pinnacle Devices, when they selected these orthopedic products to be used in surgery.

125. As a direct and proximate result of the Plaintiff's use of the Pinnacle Device, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the Pinnacle Device and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

126. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

127. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION AS AGAINST DEFENDANTS
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All Defendants)

128. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

129. Pinnacle Devices were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers,

including Plaintiff herein, of the dangerous risks and reactions associated with the device including but not limited to its propensity to cause component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, subjecting Plaintiff to risks that exceeded the benefits of the device, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, metallosis, pseudotumors, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation, disability, and discomfort, as well as the need for additional procedures to remove and replace the device, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

130. At the time of the Plaintiff's receipt and/or use of the Pinnacle Device, the Pinnacle Device was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

131. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

132. Defendants, as manufacturers and/or distributors of Pinnacle Devices, are held to the level of knowledge of an expert in the field.

133. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

134. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of Pinnacle Devices, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, metallosis, pseudotumors, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the device, as well as other severe and permanent health consequences,

notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

135. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

136. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Pinnacle Devices.

137. Had Plaintiff received adequate warnings regarding the risks of the Pinnacle Device, she would not have used it.

138. As a direct and proximate result of the Plaintiff's use of the Pinnacle Device, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the Pinnacle Device and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

139. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

140. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION AS AGAINST DEFENDANTS
NEGLIGENCE

(Against All Defendants)

141. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

142. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Pinnacle Devices into the stream of commerce, including a duty to

assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

143. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Pinnacle Devices into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

144. Despite the fact that Defendants knew or should have known that Pinnacle Devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market devices for use by consumers and/or continued to fail to comply with federal requirements.

145. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

146. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

147. Defendants' conduct as describe above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of Pinnacle Devices when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

148. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION AS AGAINST DEFENDANTS
BREACH OF EXPRESS WARRANTY

(Against All Defendants)

149. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

150. Defendants expressly warranted that Pinnacle Devices were safe and effective devices for those patients requiring a hip replacement.

151. Pinnacle Devices manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed.

152. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

153. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of Pinnacle Devices when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

154. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION AS AGAINST DEFENDANTS
BREACH OF IMPLIED WARRANTY

(Against All Defendants)

155. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

156. At the time Defendants designed, manufactured, marketed, sold, and distributed the Pinnacle Device for use by the Plaintiff, Defendants knew of the use for which the Pinnacle Device was intended and impliedly warranted the product to be of the use for which the Pinnacle Device was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

157. The Plaintiff and/or her physicians reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Device was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

158. Contrary to such implied warranty, the Pinnacle Device was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

159. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

160. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Pinnacle Device when it know or should have known of the serious health risks it created and/or

the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

161. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION AS AGAINST DEFENDANTS
NEGLIGENT MISREPRESENTATION

(Against All Defendants)

162. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

163. In the exercise of reasonable care, Defendants knew or should have known that its Pinnacle Devices failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented the Plaintiff and/or her physicians that its device was safe and met all applicable design and manufacturing requirements.

164. As a result of Defendants' reckless and/or negligent misrepresentations regarding the effects of Pinnacle Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have lead to the discovery of Defendants' wrongdoing, until shortly before this Complaint was filed.

165. The Plaintiff and/or her physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products which continue to the present day. The

Plaintiff and/or her physicians reasonably relied upon Defendants' representations that Pinnacle Devices were safe for use.

166. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Pinnacle Device, Plaintiff used Defendants' Pinnacle Device and Plaintiff suffered serious physical injury, harm, damage and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

167. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

168. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION AS AGAINST DEFENDANTS
FRAUDULENT MISREPRESENTATION

(Against All Defendants)

169. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

170. Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, and/or the FDA, and the public in general, that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

171. The representations made by the Defendants were, in fact, false.

172. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

173. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that Pinnacle Devices were safe and effective hip replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles." Defendants also advertised that the device is "[d]esigned for active lifestyles." They further asserted that the "DePuy metal-on-metal (MoM) articulation system is leading the way in advanced technology. Through years of careful engineering, research and expertise, we've created a total hip replacement solution that offers low wear and high stability." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

174. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the subject product for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

175. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff was treated with the Pinnacle Device, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

176. In reliance upon said representations, Plaintiff was induced to, and did use the subject product, thereby sustaining severe and permanent personal injuries including but not limited to significant pain, irritation and discomfort, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

177. Defendants knew and were aware or should have been aware that Pinnacle Devices had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

178. Defendants knew or should have known that Pinnacle Devices had a potential to, could, and would cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

179. Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

180. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to Pinnacle Device(s), the Plaintiff used Defendants' Pinnacle Device and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

181. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

182. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION AS AGAINST DEFENDANTS
FRAUDULENT CONCEALMENT

(Against All Defendants)

183. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

184. At all times during the course of dealing between the Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of Pinnacle Devices for their intended use.

185. Defendants knew or were reckless in not knowing that its representations were false.

186. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to the fact that:

a. the subject product was not as safe as other similar devices, drugs and medications indicated for hip arthroplasty;

b. that the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, metallosis, pseudotumors, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the device, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

c. that the subject product was manufactured negligently;

d. that the subject product was manufactured defectively;

e. that the subject product was manufactured improperly;

f. that the subject product was designed negligently;

g. that the subject product was designed defectively; and

h. that the subject product was designed improperly.

187. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of developing serious infection associates with the use of Pinnacle Devices.

188. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Pinnacle Devices, including the Plaintiff in particular.

189. Defendants' concealment and omissions of material facts concerning, *inter alia,* the safety of Pinnacle Devices was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of Pinnacle Devices, and to cause them to purchase, prescribe, dispense and/or use the subject product.

190. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

191. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

192. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Pinnacle Devices, Plaintiff used Defendants' Pinnacle Device and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

193. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

194. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION AS AGAINST DEFENDANTS
CONSUMER FRAUD – VIOLATION OF CA B&P §17200

(Against All Defendants)

195. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

196. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Plaintiff herein and her physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Pinnacle Devices, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe Pinnacle Devices for hip arthroplasty, to patients/consumers such as the Plaintiff herein. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

197. The Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

198. The Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

199. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of CA B&P §17200.

200. California has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendants knew it was defective and dangerous, and by other acts alleged herein.

201. The Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including the Plaintiff herein.

202. As a direct and proximate result of the Defendants' violations of CA B&P §17200, the Plaintiff has suffered damages, for which she is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

203. As a direct and proximate result of Defendants' conduct, the Plaintiff used Defendants' Pinnacle Device and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

204. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

205. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TWELFTH CAUSE OF ACTION
LOSS OF CONSORTIUM

(Against All Defendants)

206. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

207. Plaintiff Alan Liebowitz is lawfully married to Joan Ward, and as such, is entitled to the services, society and companionship of his spouse.

208. As a direct and proximate result of the foregoing, Plaintiff Alan Liebowitz was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff Joan Ward, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Joan Ward's injuries and damages are permanent and will continue into the future.

209. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

THIRTEENTH CAUSE OF ACTION
PUNITIVE DAMAGES

(Against All Defendants)

210. Plaintiffs readopt and reallege the allegations contained in the preceding paragraphs as though fully set forth herein.

211. At all times material hereto, the Defendants knew or should have known that their Pinnacle Devices were inherently more dangerous with respect to the risk of significant pain, irritation, discomfort, injury and need for additional surgeries than the alternative hip arthroplasty systems on the market.

212. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

213. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

214. At all times material hereto, the Defendants knew and recklessly disregarded the fact that Pinnacle Devices were subject to an increased risk of causing significant pain, irritation, discomfort, injury and need for additional surgeries in persons implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

215. Notwithstanding the foregoing, the Defendants knowingly and intentionally continued and continue to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

216. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

217. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and her surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

218. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

219. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

220. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

a. Awarding Plaintiff actual damages incidental to Plaintiff's use of the Pinnacle device in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to Plaintiffs;

c. Awarding pre-judgment and post-judgment interest to Plaintiffs;

d. Awarding the costs and expenses of this litigation to Plaintiffs;

e. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law; and

f. Granting all such other, further and/or different relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury on all issues so triable.

DATED: November 13, 2017

Yours, etc.,

CELLINO & BARNES

By: /s/ Michael J. Williams
Michael J. Williams
2500 Main Place Tower
350 Main Street
Buffalo NY 14202-3725
Ph: (800) 888-8888
Fax: (716) 854-6291
michael.williams@cellinoandbarnes.com